

DAIDS Bethesda, MD USA	POLICY	No.: DWD-POL-RA-03.00
	Requirements for Essential Documents at Clinical Research Sites Conducting DAIDS Funded and/or Sponsored Clinical Trials	Page 1 of 4
	Approval Date: 20 DEC 06 Effective Date: 05 FEB 07	Replaces: V 1.0

1.0 PURPOSE

Essential documents are those documents that individually and collectively permit evaluation of both the conduct of a clinical trial and the quality of the data produced. The purpose of this policy is to identify the Division of Acquired Immunodeficiency Syndrome (DAIDS) requirements for recordkeeping at Clinical Research Sites conducting clinical trial(s) funded and/or sponsored by DAIDS.

2.0 SCOPE

This policy applies to all Clinical Research Sites conducting DAIDS funded and/or sponsored therapeutic, vaccine, or prevention clinical trials both domestic and internationally.

3.0 BACKGROUND

Essential documents serve to demonstrate the compliance of the investigator, sponsor, and monitor with the standards of Good Clinical Practice (GCP) and with all applicable regulatory requirements. These documents are frequently audited by the sponsor and regulatory authorities as part of the process to confirm the validity of the trial conduct and integrity of the data. This policy is based on: 1) the U.S. Code of Federal Regulations (CFR), 2) regulatory guidance that applies to the involvement of human subjects in clinical trials, and 3) standards for GCP, International Conference on Harmonisation (ICH E6).

4.0 DEFINITIONS

Clinical Trials Units (CTUs) - are entities composed of an administrative component and one or more Clinical Research Sites that contribute to the Network clinical research plan by conducting the clinical research (that is, executing clinical protocols). CTUs also may contribute scientific and clinical research expertise to the development of the Network clinical research plan. CTUs are responsible for developing and maintaining effective community relationships; enabling community participation in Clinical Research Sites, CTU, and Network activities; and ensuring that all clinical research is conducted in compliance with Network bylaws, policies and procedures, DAIDS policy and procedures, federal regulations, and any applicable local requirements.

Clinical Research Sites - are discrete locations (e.g. hospitals, outpatient clinics, health maintenance organizations, community health centers, private practices, clinics, etc.) where qualified professionals conduct clinical research in accordance with GCP.

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For additional definitions see DAIDS glossary.

5.0 RESPONSIBILITIES

It is the responsibility of DAIDS program staff to assist and provide guidance to grantees and site staff regarding recordkeeping and retention, as appropriate.

It is the responsibility of the Principal Investigator to ensure the site staff is trained in GCP to include record retention, and that clinical research sites conducting clinical trials sponsored and/or funded by DAIDS adhere to this policy.

It is the responsibility of the Principal Investigator or designee to maintain records consistent with this policy, and federal, state and local regulations as applicable.

6.0 POLICY

- 6.1. The document “Essential Documents Recordkeeping Requirements” (Appendix 1) describes DAIDS Clinical Research Site recordkeeping requirements. In addition to a complete list of essential documents, it includes a full description of: 1) the purpose and/or requirement of each document, 2) a recommendation as to whether the document should be filed in a central file, protocol files, pharmacy file, laboratory file, or in subject records, and 3) reference to the pertinent federal regulation(s) or guidance for each type of document.
- 6.2. The essential documents should be set up in a secure central location at the beginning of the trial and maintained throughout the trial. It is acceptable to combine some of the documents, as long as the individual elements are readily identifiable. All documents do not have to be combined into one regulatory file.
- 6.3. Regulatory files must be maintained for all trial sites. It is acceptable for a Clinical Trials Unit to maintain regulatory files for their affiliated clinical research sites if necessary.
- 6.4. All documents identified in this policy and attached appendix must be available for audit/inspection by the sponsor and regulatory authorities.
- 6.5. Documents may be saved in an electronic format when appropriate.
- 6.6. Resource tools (e.g., lab processing charts) are not included as essential documents.

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- 6.7. In addition to DAIDS requirements, clinical research sites are expected to comply with local, state, institution, and/or institutional review board (IRB)/independent ethics committee (IEC) policies and regulations and follow any procedures that are more stringent than those of DAIDS.
- 6.8. Timelines for record retention established in U.S. Federal regulations such as 21 CFR 312.57 and 312.62 and 45 CFR 46.115 are considered minimum durations and are frequently superseded by other policy. Retention or destruction of essential documents must be in accordance with local institution/IRB/IEC policies and procedures. No clinical research files should be destroyed without consulting DAIDS and current DAIDS policy.

7.0 REFERENCES

U.S. Code of Federal Regulations, Title 45, Part 46 and Subparts B, C, and D
<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>

International Conference on Harmonisation, Guidance for Industry, E6 Good Clinical Practice: Consolidated Guidelines
<http://www.fda.gov/oc/gcp/guidance.html>

U.S. Code of Federal Regulations, Title 21, Parts 11, 50, 54, 56, and 312
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>

8.0 INQUIRIES

Questions and comments regarding this policy may be directed to the OPCRO Policy Group at: NIAIDOPCROPOLICYGROUP@mail.nih.gov

9.0 AVAILABILITY

This policy is available electronically at the following URL:
<http://www3.niaid.nih.gov/research/resources/DAIDSClinRsrch/Default.htm>

The signed original is maintained in the OPCRO policy office.

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10.0 CHANGE SUMMARY

Version #	Date	Replaces	Date of Revision	Rationale for Revision/Retirement
2.0	20 DEC 06	V 1.0	20 DEC 06	DAIDS Final Review
1.0	14 JUL 06	N/A	N/A	N/A

11.0 APPENDICES

Appendix 1 – Essential Documents Recordkeeping Requirements

12.0 APPROVAL

Signature	Program/Branch	Date
<p>Authorized By: </p> <hr/> <p>Richard Hafner, MD Director</p>	<p>Office for Policy in Clinical Research Operations (OPCRO)</p>	<p>December 20, 2006</p> <hr/>